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09/991,407	11/16/2001	Anthony DiSalvo	PPC-812	3311

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EXAMINER
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KIDWELL, MICHELE M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/09/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/991,407

Applicant(s)

DISALVO ET AL.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3,5-6.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's arguments, see page 2, 5<sup>th</sup> paragraph filed December 5, 2003, with respect to claims 1 – 20 have been fully considered and are persuasive. The restriction and election of species requirement of claims 1 – 20 has been withdrawn.

After another review of the specification and claims in combination with the traversal arguments presented by the applicant, the examiner has decided to withdraw the previous restriction and election of species requirement.

### ***Information Disclosure Statement***

The information disclosure statement filed January 29, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the U.S. applications have not been identified by the inventor and the filing date.

37 CFR 1.98 states that:

Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.

It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the

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statement, including all certification requirements for statements under 37 CFR 1.97(e).

See MPEP § 609 ¶ C(1).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

· A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 2, 6 – 15, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bucalo (US 4,232,673).

With respect to claim 1, Bucalo discloses an absorbent device for insertion into a vaginal cavity (col. 8, lines 36 – 40), the absorbent device comprising an absorbent body (136) and an indicator structure arranged and configured within the absorbent body (figure 12), the indicator structure comprising a resilient member (138) maintained in a strained configuration by a restraint (140); wherein the resilient member is capable of reverting to a relaxed configuration upon the weakening of the restraint and the restraint weakens upon exposure to moisture as set forth in col. 8, lines 40 – 44 and 51 – 59.

With reference to claim 2, Bucalo discloses an absorbent device wherein the absorbent body comprises absorbent material as set forth in col. 8, lines 36 – 38.

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Regarding claim 6, Bucalo discloses an absorbent device wherein the restraint maintains the resilient member in a compressed configuration as set forth in col. 8, lines 45 – 48 and in figure 12.

With reference claim 7, Bucalo discloses an absorbent device wherein the restraint maintains the resilient member in a stretched configuration as set forth in col. 4, lines 28 – 33.

As to claim 8, Bucalo discloses an absorbent device wherein the restraint maintains the resilient member in a bent configuration as set forth in col. 8, lines 45 – 48 and in figure 12.

With respect to claim 9, Bucalo discloses an absorbent device wherein the resilient member is in the shape of a ring as set forth in figure 12.

With reference to claim 10, Bucalo discloses an absorbent device wherein the resilient member is a spring as set forth in col. 8, lines 42 – 44.

Regarding claim 11, Bucalo discloses an absorbent device wherein the resilient member is formed of plastics, metals and combinations thereof as set forth in col. 8, lines 40 – 42.

With respect to claim 12, Bucalo discloses an absorbent device wherein the restraint comprises a water soluble material as set forth in col. 8, lines 19 – 22.

As to claim 13, Bucalo discloses an absorbent device wherein the restraint comprises gelatin as set forth in col. 8, lines 19 – 22.

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With respect to claim 14, Bucalo discloses an indicator device comprising a resilient member (138) maintained in a strained configuration by a restraint (140) wherein the resilient member is capable of reverting to a relaxed configuration upon weakening of the restraint and the restraint weakens upon exposure to moisture as set forth in col. 8, lines 42 – 50.

With reference to claim 15, Bucalo discloses a method of absorbing aqueous vaginal fluids comprising the steps of a) inserting a first absorbent device into a vaginal cavity, the absorbent device comprising an absorbent body (136) and an indicator structure arranged and configured within the absorbent body (figure 12), the indicator structure comprising a resilient member (138) maintained in a strained configuration by a restraint (140), wherein the resilient member is capable of reverting to a relaxed configuration upon the weakening of the restraint and the restraint weakens upon exposure to moisture (col. 8, lines 40 – 44 and 51 – 59;

b) allowing the first absorbent device to absorb sufficient aqueous vaginal fluids to weaken the restraint and to permit the resilient member to revert to the relaxed condition (col. 9, lines 12 – 17 and 38 – 43); c) detecting changed dimensions of the first absorbent device caused by the reversion of the resilient member to the relaxed configuration and d) removing the first absorbent device from the vaginal cavity as set forth in col. 9, lines 41 – 49.

The examiner contends that in order for the tampon to be removed from the body cavity (col. 9, line 44) that the tampon must be first inserted. Further, the detection of the changed dimensions (i.e. the expansion of the container after the fluid has allowed

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the band to dissolve) is visibly detected when the user removes the tampon from the vaginal cavity.

Regarding claim 17, Bucalo discloses method for making an absorbent device comprising the steps of manipulating a resilient member into a deformed condition; b) applying a restraint to maintain the resilient member in the deformed condition and to form an indicator structure and forming an absorbent body containing the indicator structure as set forth in col. 8, lines 36 – 48.

With respect to claim 20, Bucalo discloses an absorbent device wherein the absorbent body has a shape, and the relaxed configuration distorts the shape of the absorbent body in a manner discernible to a user as set forth in figures 12 – 13.

The examiner contends that the shape distortion of the absorbent device can at least be discerned by the user observing the absorbent device prior to insertion and upon removal to visibly detect the change in shape caused by the expansion of the container.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 – 5, 16 and 18 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo (US 4,232,673).

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The difference between Bucalo and claim 3 is the provision that the absorbent material is formed of fibers, foams or combinations thereof.

It would have been obvious to one of ordinary skill in the art to form the absorbent material of Bucalo from fibers, foams or combinations thereof because Bucalo states that the tampon may be made of any suitable absorbent material (col. 8, lines 35 – 37) and the use of fibers, foams or combinations thereof for the formation of absorbent material is extremely well known in the art.

As to claim 4, Bucalo teaches an absorbent device wherein the fibers are hydrophilic as set forth in col. 8, lines 36 – 38.

Regarding claim 5, Bucalo teaches an absorbent material wherein the fibers are absorbent as set forth in col. 8, lines 36 – 38.

With reference to claim 16, Bucalo substantially discloses the invention as claimed.

While Bucalo does not explicitly state that a second absorbent device is inserted into the vaginal cavity after the first absorbent device is removed from the vaginal cavity, the examiner contends that it would have been obvious to one of ordinary skill in the art to insert a second absorbent device into the vaginal cavity after the first absorbent device is removed because the course of a normal menstrual cycle spans five days. The use of one absorbent device would not be usable over the entire course of the menstrual cycle due to continuous bleeding and Toxic Shock Syndrome risks.



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Further, if the user needed duplicate samples of menstrual fluid for testing purposes, then a second absorbent device would have to be placed into the vaginal cavity after the first absorbent device is removed as suggested by Bucalo in col. 7, lines 39 – 43.

The difference between Bucalo and claim 18 is the provision that the absorbent body is formed around the indicator structure.

The difference between Bucalo and claim 19 is the provision that the absorbent body is formed and the indicator structure is inserted therein.

The examiner has consulted the instant specification and concludes that forming the absorbent body around the indicator structure or forming the absorbent body and then inserting the indicator structure does not solve any stated problem or produce any unexpected result and it appears that the absorbent device will perform equally well in either instance.

It would be obvious to one of ordinary skill in the art to either form the absorbent body around the indicator structure or form the absorbent body and insert the indicator structure therein since it has been held that rearranging parts of an invention involves only routine skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michele Kidwell  
March 8, 2004